

REMARKS

Claims 9-15 and 17 are pending the application; Claims 9-15 and 17 stand rejected under 35 USC §102b.

Claims 9-15 and 17 stand rejected under 35 USC 102b over Kuznicki; Applicant respectfully traverses these rejections. Kuznicki discloses a beverage composition (much like gatorade) specifically addressed to the matter of "dehydration relative to water in individuals" and "rapid cellular hydration" that contains, in addition to flavanols, many other ingredients, such as electrolytes and carbohydrates. The disclosures of Kuznicki are not directed to therapeutics for diseases of any sort. The cognitive improvement disclosed is not any kind of therapeutic to a pathological condition, but rather a remedy to the fuzziness of thought that typically accompanies dehydration in some individuals. This is no kind of teaching of suggestion that such a mixture would have any effect at all on the kind of cognitive impairment that accompanies Alzheimer's disease.

Kuznicki does NOT address any kind of general cognitive improvement with his formulation, but rather a very specific "increased cognitive performance after heat dehydration" addressed apparently to that well-known phenomenon of specific mental fuzziness upon significant dehydration. The kind of restoration of mental freshness attendant upon a proper rehydration of the body's cells after exercise, bears no relation whatever to cures for any of the kinds of cognitive impairments that occur in the claimed therapeutic areas, either pathologically or in any other physical or chemical sense. At col.3, lines 36-37 (right after the location cited by the Examiner) Kuznicki actually specifies that the improvements disclosed are believed to be related to the flavanols' effect simply in enhancing cellular rehydration. There is therefore no basis whatever to suppose that a drink of Kuznicki's beverage would have any effect, inherently or otherwise, on any of the conditions claimed. Therefore, Kuznicki neither teaches nor suggests a therapeutic for the claimed conditions, and the claims are thus distinguished over the cited art. Reconsideration is requested.

Claim 17 is especially distinguished over the cited art by substituting the words "consisting of" for the word "comprising" in original claim 1. Thus Claim 17 can not be read upon the

formulations of Kuznicki because those formulations have ingredients other than catechins and excipients and the like. Applicant respectfully submits that the Examiner's characterization of fruit juice, flavoring, sodium citrate and the like (all of which are quite common beverage ingredients) as if they were 'excipients' is a stretch beyond any common understanding of the meaning of the term "excipient" as it is used by those of ordinary skill in the art. These listed ingredients are NOT excipients, they are beverage enhancements, and claim 17 therefore does not read on a composition containing any such ingredients. The Examiner's assertion that the reference discloses a composition having the same ingredients in the same amount therefore does not apply to Claim 17 and it is therefore distinguished over the cited art because the cited art teaches that catechins solutions should contain any number of other additives; Claim 17 is believed to be in condition for allowance, and reconsideration is requested.

Claims 9, 12-15 and 17 stand rejected under 35 USC 102 over Mitsui Norin JP patent 10245342 of record; Applicant respectfully traverses these rejections. Mitsui Norin discloses only a toxicity diminishing effect on beta-amyloid protein; there is no discussion or suggestion of any effect on fibrillogenesis of amyloid or alpha-synuclein or NAC fibrils. Applicant respectfully submits that, at the time of the priority date of these claims, reducing toxicity had no established connection in the art to inhibiting or reversing fibril or plaque formation, and there is also no basis in the art of that time to establish or predict any degree of inherency. Specifically, there is no way to tell with any certainty that a formulation proposed by Mitsui Norin to reduce amyloid toxicity would also and at the same time necessarily have the effect of inhibiting or reversing amyloid fibrillogenesis, much less alpha-synuclein or NAC fibrillogenesis. The Examiner asserts that Mitsui discloses the same ingredients, but Mitsui discloses no therapeutic efficacy for anti-fibrillogenesis, and therefore can not be regarded as disclosing the same ingredients. None of the disclosed ingredients have been shown or even suggested to have any anti-fibrillogenic efficacy.

This is especially the case with Claim 17 which is specifically directed to a composition "consisting of", i.e. limited to, the recited ingredients. Claim 17 does not read on Mitsui's "cup of green tea" because such a beverage would have more ingredients than just catechin. As with

Kuznicki above, Claim 17 cannot be read upon Mitsui Norin, and is therefore believed to be allowable.

With regard to the Examiner's discussion and remarks about 'inherency', there appear to be two separate lines of authority with respect to notions of inherence as bars to patentability. In one line, certain claim elements, not expressly contained in a cited prior art reference are said to be inherently present in the structure disclosed in the reference and that the claim therefore reads fully upon the reference. This is a line of cases articulating a strong public policy of not depriving or divesting the public of rights arguably already theirs by virtue of a previous public disclosure. For instance in *Atlas Powder v. Ireco*, 190 F.3d 1342; 51 USPQ 2d 1943 (Fed.Cir. 1999), a case involving explosive formulations, certain claimed formula ingredient (aeration) ranges were determined to be inherent in the prior art structures of similar explosives. Implicitly in the *Atlas* case and others like it, the public policy of not depriving the public of rights given in a prior art disclosure is upheld, because it was determined in effect in *Atlas* that every subsequent user or manufacturer of the prior art explosive formulation would necessarily be infringing the new claim if it was allowed over the prior art reference.

But in another line of cases, different from the *Atlas* type cases in that no public policy issues are presented, application by the Patent Office of inherence as a ground of rejection is reversed because the mere possibility of inherence is not the same as inherence in fact. For instance in *In re Robertson*, 169 F.3d 743; 49 USPQ 2D 1949 (Fed.Cir. 1999), a case involving diaper fasteners, the court reversed a Board of Patent Appeals affirmation of an inherence rejection of claims, saying, "To establish inherence the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. [emphasis added]" The court also said, "Inherency however may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient [emphasis added]." This is thus clearly a 1999 reversal, *sub silentio*, of anything that might appear to the contrary in the old 1977 *In re Best* case cited by the Examiner.

Unlike the facts in *Atlas*, public policy is actually served, not vitiated, by allowing new claims to a cure for Alzheimer's Disease and the like, for the public did not previously have access to such a cure. Thus the *Robertson* case controls here, and the present claims and their relation to the cited references present a case within the ambit of this *Robertson* type of case. That is, while it might be the case (but which Applicant must here deny, since it is not established and probably can not be established) that a dose of Kuznicki's drink, or Mitsui's compositions, could have a therapeutic effect on a patient having an amyloid condition, it is only speculative at best, a mere possibility, and therefore not "necessarily present" in these cited references. And even if it could be said to be necessarily present, it would certainly not be "so recognized by persons of ordinary skill". Since "ordinary level of skill" has to be defined prior to the claimed invention, no one skilled in the art as it stood before the present invention would have recognized the anti-amyloid properties of any of the compositions disclosed by the cited art. This is just the type of situation contemplated by the *Robertson* court, in that the public is in no danger in this case of losing something they had before; there is no conflict and no loss of public right, only gain.

Thus under the *Robertson* line of cases, and the correctly understood public policy considerations underlying inherence determinations, "inherence" can not be applied to read into the cited references' disclosures any efficacy for other catechin compositions as therapeutics for amyloidoses. Since such a surprising efficacy was not necessarily contained in the cited disclosure, and no one skilled in the art would have so recognized any such new efficacy, the present claims are therefore distinguished over the cited references, and this rejection should be reversed.

Indeed in the seminal inherence case of *In re Shetty*, 566 F.2d 81; 195 USPQ 753 (CCPA 1977), a case reversing the Board of Appeals application of the doctrine of inherence as to claims drawn to an appetite suppressant and rejected over an similar compound that functioned as an antiviral agent, the venerable Judge Rich says, "The inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown." He also says that inherency "is quite immaterial if ... one of ordinary skill in the art would not appreciate or recognize that inherent

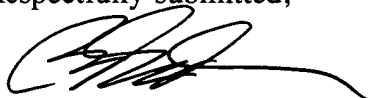
result.” This view survives to the present and is the same as that expressed in the *Robertson* case discussed above.

Claims 9-15 and 17 stand rejected as allegedly subject to obviousness-type double patenting. Applicant submits in response that it will file the appropriate terminal disclaimer upon an indication of allowable subject matter in this case.

Applicant believes that it has responded fully to all of the concerns expressed by the Examiner in the Office Action, and respectfully requests that new Claims be entered and examined, and that early favorable action be taken on all claims pending in the application. Applicant respectfully requests reexamination of all rejected claims and early favorable action on them as well. If the Examiner has any further concerns, Applicant requests a call to Patrick Dwyer at (206) 343-7074.

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Respectfully submitted,



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